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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/913,814

09/19/2002

Glen Patrick Martyn

GJE-6035

4398

23557

7590

06/15/2006

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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,814	MARTYN ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9 and 11-13 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1,4-9 and 11-13 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of continued examination dated 3-20-06 is acknowledged.

Claims 1, 4-9 and 11-13 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 3-20-06 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1, 4-9 and 11-13 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

Claims 1, 7, 9 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,824,938 to Koyama et al (Koyama).

Koyama discloses a water-soluble composition comprising a bioactive substance, TNF, stabilized by the presence of a polysaccharide, pullulan (col. 2, lines 25-56 and col.5, lines 40-44 and examples 1 and 2). Examples 1 and 2 of Koyama disclose that the pullulan and active agent containing composition is freeze-dried in a glass vial, which reads on the claimed shaped-body. Thus, Koyama anticipates instant claims.

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Claims 1, 4 7, 9 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 53012417 (JP).

JP discloses a sub-amorphous rugs prepared by adding pullulan to the aqueous drug solution a freeze-drying (abstract), to produce a rapidly dissolving product. JP discloses addition of water and indomethacin, which read on instant excipient and active agent. While JP does not explicitly mention a shaped body, JP discloses freeze-drying the composition, which can only be done in a container such as a vial and will inherently result in the shape of the vial upon freeze-drying. Thus, JP anticipates instant claims.

Claim Rejections - 35 USC § 103

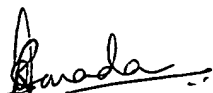
Claims 4-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,824,938 to Koyama et al (Koyama).

Koyama discussed above does not exemplify a tablet or addition of another carbohydrate and other excipients of instant claims. However, Koyama suggests adding additional substances such as polysaccharides, amino acids, buffers, minerals etc., to the composition (col. 2, lines 56-60). Koyama also suggests preparing the composition for internal and external treatment and in the form of tablets, suppositories, granule, injections etc (abstract, col. 6, lines 31-33, col. 8, lines 13-17). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention that it is conventional in the pharmaceutical art to include additional polysaccharides, buffers, minerals etc and also substances such as colors or flavors as desired in the composition of

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Koyama and prepare the composition in the form of a tablet or other pharmaceutical dosage forms depending on the route of administration chosen without losing the stability of the composition afforded by pullulan because suggests that pullulan can be employed as a stabilizer to various dosage forms containing a proteinaceous active substances and that the compositions may desirably contain additional excipients or substances.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

May 22, 2006